UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

TEXAS ASSOCIATION FOR HOME CARE & HOSPICE; INDIANA ASSOCIATION FOR HOME & HOSPICE CARE; ASSOCIATION FOR HOME & HOSPICE CARE OF NORTH CAROLINA; SOUTH CAROLINA HOME CARE & HOSPICE ASSOCIATION; and HOUSTON HOSPICE, Plaintiffs, v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Case No.:

COMPLAINT AND APPLICATION FOR A PRELIMINARY INJUNCTION OR STAY OF AGENCY ACTION

Plaintiffs, by and through undersigned counsel, bring this action against Defendant Xavier Becerra in his official capacity as the Secretary of the United States Department of Health and Human Services ("HHS") and against Defendant HHS, and state as follows:

INTRODUCTION

1. Plaintiffs bring this action to request that the Court preliminarily and permanently declare unlawful and set aside Defendants' promulgation of (1) the Hospice

Special Focus Program Final Rule and (2) the Hospice Special Focus Program List, along with its accompanying data.

2. Plaintiffs represent high-quality hospice programs that each have a mission of promoting the well-being of terminally ill patients and their families at a most fragile phase of their lives. Plaintiffs actively support efforts to improve oversight of hospice providers, especially ones that provide poor care or operate fraudulently. But Defendants' publication of a list of "poor performing" hospices is so arbitrary and flawed that it will make it harder for patients and families to find trustworthy providers. Defendants' actions convey a false narrative that "Special Focus Program" providers may be unsafe or dangerous, sowing fear among their current patients and "survivor's guilt" among family members whose loved ones passed away in the care of a listed provider. Just as troubling, Defendants' arbitrary list sends an implicit approval of truly low-quality or unethical providers who are not listed. This Court's intervention is essential.

3. Plaintiffs represent reputable hospice programs throughout Texas, Indiana, North Carolina, and South Carolina who are committed to providing compassionate, ethical, and quality care to patients and families. Plaintiffs include Houston Hospice, the city's oldest and largest non-profit hospice provider, which has earned the trust of countless patients and families. Last year, Houston Hospice served an average of 190 patients per day and has a strong record of quality and compliance. That is true even as Houston Hospice cares not only for patients at home but also for patients in an in-patient facility staffed with well-trained medical professionals. Incredibly, however, Defendants selected Houston Hospice for inclusion on the Special Focus Program List of 50 "poor performing" hospices from around the entire country.

4. To be sure, there is a real problem with a subset of hospice programs that provide poor care or operate unethically. For example, a recent *Hospice News* article reported that "[f]raudulent hospices in California [ ] have been targeting homeless people and methadone patients, promising them a steady supply of opioids in exchange for enrolling in hospice."[1]

5. In recent years, certain States (Arizona, California, Nevada, and Texas) have seen rapid growth in new hospice providers, far outstripping demand.[2] A 2022 California State Auditor Report found widespread indications of fraudulent hospice providers in Los Angeles County, such as a single building that reportedly had over 150 licensed hospice and home health agencies—more than the building's physical capacity.[3] According to the Report, hospice agencies in the County had an average of *fewer than five patients per day,* compared to the state average of 56 patients per day. Further, California's initial licensing process did not require adequate screening to ensure new hospice providers were qualified to provide services.[4] And then California failed to adequately investigate complaints of patient neglect or abuse.[5] In response to these findings, California state officials imposed a moratorium on

[1] Jim Parker, *Fraudulent Hospice Reportedly Target Homeless People, Methadone Patients to Pad Census*, HOSPICE NEWS (Aug, 23. 2024), available at https://hospicenews.com/2024/08/23/fraudulent-hospices-reportedly-target-homeless-people-methadone-patients-to-pad-census/ (last visited Jan. 15, 2025).

[2] *See* Ava Kofman, *Hospices in Four States to Receive Extra Scrutiny Over Concerns of Fraud, Waste and Abuse*, PROPUBLICA (July 21, 2023), available at https://www.propublica.org/article/hospices-arizona-california-nevada-texas-cms-medicaid-medicare (last visited Jan. 15, 2025).

[3] *See* Cal. State Auditor Rep. 2021-123, *California Hospice Licensure and Oversight: The State's Weak Oversight of Hospice Agencies Has Created Opportunities for Large-Scale Fraud and Abuse*, at 1 (Mar. 2022), available at https://www.documentcloud.org/documents/23318778-2022_ca_audit_report/ (last visited Jan. 15, 2025).

[4] *See id.* at 2.

[5] *See id.* at 2.

new hospice licenses. Still, against that backdrop, Defendants' selection of providers like Houston Hospice for the Special Focus Program List is galling.

6. Defendants' actions also badly stray from Congress's directives. To strengthen oversight of hospices, in 2020, Congress instructed HHS to establish a "special focus program" (SFP) to enhance enforcement for a subset of hospices that "the Secretary has identified as having substantially failed to meet" Medicare requirements. 42 U.S.C. § 1395i-6(b).[6]

7. Despite that clear statutory mandate, HHS promulgated the Hospice Special Focus Program Final Rule that adopted an algorithm to select hospices for the SFP that includes not only findings of noncompliance with Medicare requirements but also indicators *other than* noncompliance. *See* CMS, *Calendar Year 2024 Home Health Prospective Payment System Final Rule*, 88 Fed. Reg. 77,676, 77,879 (Nov. 13, 2023) (promulgating 42 C.F.R. § 488.1135). Those other indicators—(1) the Consumer Assessment of Healthcare Providers and Systems ("CAHPS") survey, and (2) the Hospice Care Index ("HCI")—do not measure whether a hospice provider is in violation of a Medicare requirement. Moreover, the Final Rule's use of them skews the results towards larger, established providers and away from smaller or new providers.

8. In addition, the algorithm makes no adjustments for size of hospice provider in counting the number of substantiated complaints a provider had, meaning that larger providers who had a relatively smaller percentage of complaints per patients served are treated the same as a small provider who had a larger percentage of complaints per patients it served.

[6] *See* Consolidated Appropriations Act of 2021, Pub. L. 116-260, § 407, 134 Stat. 1182, 3003 (Dec. 27, 2020).

9. After Defendants first proposed what became the Final Rule in July 2023, numerous voices from the hospice community submitted comments to CMS pointing out multiple flaws with CMS's algorithm and data inputs. Nonetheless, in November 2023, CMS proceeded to adopt the flawed Final Rule and algorithm as proposed. The problems with CMS's approach were so apparent that members of Congress and leaders of the hospice community called on CMS to delay proceeding with the Special Focus Program List selections to give more time for flaws to be addressed.[7]

10. Although Congress placed no deadline on CMS to issue the Special Focus Program List, *see* 42 U.S.C. § 1395i-6(b), CMS pressed forward to publicize the List nonetheless. On or about December 18, 2020, Defendants notified some fifty (50) hospice providers that they would be selected for the Special Focus Program. CMS offered no procedure for these providers to correct errors in CMS's data leading to their selection or to appeal their selection for the Program. And on December 20, 2024, Defendants posted on the CMS website the Hospice Special Focus Program List, publicizing to the world the 50 hospices selected from across the country as "poor performers."[8] Together with this Hospice Special Focus Program List, CMS released its "underlying data" that was used to create the list and that would be used to identify "future SFP candidates."[9]

11. The arbitrariness of Defendants' approach is compounded by the fact that CMS's "underlying data" is rife with errors. For example, CMS's data list certain hospices as having substantiated complaints involving violations of Medicare requirements when, in

[7] *See infra*, Legal and Factual Background, Part F.
[8] See Hospice Special Focus List, available at https://www.cms.gov/medicare/health-safety-standards/certification-compliance/hospice-special-focus-program (last visited Jan. 15, 2025).
[9] See Hospice Special Focus List, available at https://www.cms.gov/medicare/health-safety-standards/certification-compliance/hospice-special-focus-program (last visited Jan. 15, 2025).

fact, the complaints involved only State licensure issues or were not substantiated at all. Indeed, in less than three weeks since first publishing the Special Focus Program List, Defendants have changed the List twice, removing four initially listed programs and adding four others.

12. Defendants' actions violate the Administrative Procedure Act ("APA"): the Final Rule and List are contrary to law and were promulgated in excess of the Secretary's statutory authority, violating 5 U.S.C. § 706(2)(C); are arbitrary and capricious, violating 5 U.S.C. § 706(2)(A); and were promulgated without observance of procedure required by law, violating 5 U.S.C. § 706(2)(D).

13. Plaintiffs seek preliminary and permanent declaratory and injunctive relief, including setting aside the Hospice Special Focus Program Final Rule and List, enjoining the Special Focus Program, and ordering Defendants to withdraw the List and underlying data immediately.

PARTIES

14. Plaintiff Texas Association for Home Care & Hospice is a non-profit corporation organized under the laws of the State of Texas with its principal place of business located at 9390 Research Blvd, Bldg. I, Suite 300, Austin, TX 78759.

15. Plaintiff Indiana Association for Home & Hospice Care is a non-profit corporation organized under the laws of the State of Indiana with its principal place of business located at 6320-G Rucker Road, Indianapolis, IN 46220.

16. Plaintiff Association for Home & Hospice Care of North Carolina is a non-profit corporation organized under the laws of the State of North Carolina with its principal place of business located at 1511 Sunday Drive, Suite 318, Raleigh, NC 27607.

17. Plaintiff South Carolina Home Care & Hospice Association is a non-profit corporation organized under the laws of the State of South Carolina with its principal place of business located at 1511 Sunday Drive, Suite 318, Raleigh, NC 27607.

18. Texas Association for Home Care & Hospice, Indiana Association for Home & Hospice Care, Association for Home & Hospice Care of North Carolina have members who have been included in the Hospice Special Focus Program.[10] The Association Plaintiffs—Texas Association for Home Care & Hospice, Indiana Association for Home & Hospice Care, Association for Home & Hospice Care of North Carolina, and South Carolina Home Care & Hospice Association—each advocate on behalf of their members with state and federal regulators.[11] This advocacy is a central part of their organizational missions and an important benefit to their members.[12]

19. Plaintiff Houston Hospice is a non-profit organization organized under the laws of the State of Texas with its principal place of business located at 1905 Holcombe Blvd, Houston, TX 77030.

20. Defendant Xavier Becerra is the Secretary of the United States Department of Health and Human Services ("HHS"). He is sued in his official capacity. The Secretary administers the Medicare program through the Centers for Medicare and Medicaid Services ("CMS"), which is an agency within HHS.

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[10] Ex. 3, Declaration of Rachel Hammon, ¶ 8 (hereinafter "Hammon Decl."); Ex. 4, Declaration of Evan Reinhardt, ¶ 11 (hereinafter "Reinhardt Decl."); Ex. 5, Declaration of Timothy R. Rogers, ¶ 9 (hereinafter "AHHC Decl.").

[11] Ex. 3, Hammon Decl., ¶¶ 3, 4; Ex. 4, Reinhardt Decl., ¶ 7; Ex. 5, AHHC Decl., ¶ 3; Ex. 6, Declaration of Timothy R. Rogers, ¶ 5 (hereinafter "SCHCHA Decl.").

[12] Ex. 3, Hammon Decl., ¶ 4; Ex. 4, Reinhardt Decl., ¶¶ 6-7; Ex. 5, AHHC Decl., ¶¶ 3, 5; Ex. 6, SCHCHA Decl., ¶¶ 3, 5.

21. Defendant United States Department of Health and Human Services is the department of the federal government ultimately responsible for the federal Medicare and Medicaid programs.

JURISDICTION AND VENUE

22. This Court has jurisdiction over this action under 28 U.S.C. § 1331 because this action arises under the APA, 5 U.S.C. §§ 701 *et seq.*

23. Venue is proper pursuant to 28 U.S.C. § 1391(e)(2)-(3) because this is an action against officers and agencies of the United States, a substantial part of the events giving rise to certain Plaintiffs' claims occurred in this District, and Plaintiff Houston Hospice resides in this District.

24. The Complaint is timely under 28 U.S.C. § 2401(a).

LEGAL AND FACTUAL BACKGROUND

A. The Medicare Certification and Survey Process

25. The Medicare program, authorized under Title XVIII of the Social Security Act, is a federal program that provides health insurance benefits for Americans aged 65 years and older and certain disabled persons. *See* 42 U.S.C. §§ 1395 *et seq.*

26. The Medicare program includes a hospice benefit that covers an interdisciplinary set of services for patients who are terminally ill, *i.e.* those who have been certified by a physician to have a medical prognosis of six months or less if their illness runs its normal course. *See* 42 U.S.C. § 1395x(dd)(3)(A).

27. Medicare covers only those hospice services that are provided by Medicare-certified hospice programs. *See* 42 U.S.C. §§ 1395d, 1395x(dd).

28. To become Medicare-certified, a hospice must undergo a survey by a state survey agency to demonstrate that it satisfies the requirements to participate as a hospice in the Medicare program. *See* 42 C.F.R. §§ 418.1, 424.510, 488.3.

29. In lieu of having a survey performed by a state survey agency, a hospice may seek "deemed status" from a national accrediting organization. *See* 42 U.S.C. § 1395bb. When a hospice opts for the accreditation route, the accrediting organization, rather than state survey agency, performs the survey and determines that the hospice program satisfies the requisite conditions of participation for Medicare.

30. The statutory requirements to be certified as a hospice program are located at 42 U.S.C. § 1395x(dd). These include providing certain types of care on a 24-hour basis, 42 U.S.C. § 1395x(dd)(2)(A), having a hospice interdisciplinary group, *id.* § 1395x(dd)(2)(B), maintaining clinical records, § 1395x(dd)(2)(C), not discontinuing care due to an inability to pay, § 1395x(dd)(2)(D), using volunteers appropriately, § 1395x(dd)(2)(E), maintaining specified licenses, § 1395x(dd)(2)(F), and complying with the requirements that CMS determines necessary for patients' health and safety, § 1395x(dd)(2)(G).

31. Pursuant to its statutory authority, CMS has prescribed additional requirements for Medicare certification at 42 C.F.R., part 418, subparts B, C and D (§§ 418.20-.114). These regulatory requirements are often referred to as conditions of participation.

32. After the initial survey and certification process, hospices are subject to ongoing surveys to ensure that they continue to meet Medicare's statutory and regulatory requirements. 42 C.F.R. § 488.1110(a).

33. While surveys must be conducted at least once every three years, they may be conducted as frequently as necessary to "[a]ssure the delivery of quality hospice program services by determining whether a hospice program complies with the Act and conditions of participation" and to "[c]onfirm that the hospice program has corrected deficiencies that were previously cited." *Id.*

34. Surveys are also conducted anytime that a complaint against the hospice is reported to CMS or a state or local survey agency. 42 C.F.R. § 488.1110(b).

35. During a survey, the surveyor will determine whether the hospice has any deficiencies, which are defined as violations of Medicare statutory requirements or the conditions of participation located at 42 C.F.R. § 418, Parts C and D. *See* 42 C.F.R. § 488.1105 (defining "deficiency").

36. Depending on their severity, deficiencies may be either condition-level or standard-level. *Id.*

37. A condition-level deficiency means that the deficiency is "of such character as to substantially limit the provider's or supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients." *See* 42 C.F.R. §§ 488.1005, 488.24.

38. A standard-level deficiency means "noncompliance with one or more of the standards that make up each condition of participation for hospice programs." 42 C.F.R. § 488.1105 (defining "Standard-level deficiency").

39. Hospices may be subject to enforcement action depending on the nature, degree, frequency, and impact of the deficiency. *See* 42 C.F.R. § 488.1215.

40. Available enforcement actions against hospices with deficiencies include payment suspensions, civil money penalties, and termination of the hospice's provider agreement, among other things. *See* 42 C.F.R. § 488.1220.

B. Congress Strengthens Medicare's Survey-and-Enforcement Scheme for Hospices.

41. In 2019, the HHS Office of Inspector General ("OIG") issued a report titled *Hospice Deficiencies Pose Risks to Medicare Beneficiaries.*[13] The report reviewed results from survey agencies and accrediting organizations, and found over 80 percent of hospices had at least one deficiency, meaning they failed to substantially comply with a requirement for participating in the Medicare program.[14] The report found that over 300 hospices (18%) had surveys showing at least one serious deficiency or at least one substantiated severe complaint, which the report deemed to be the "poor performers."[15] As a result, HHS OIG recommended that CMS strengthen the survey process, provide more information to beneficiaries, and increase oversight of hospices with a history of serious deficiencies.[16]

42. The 2019 OIG Report prompted Congress to develop legislation to implement OIG's recommendations. *See Helping Our Senior Population in Comfort Environments (HOPSICE) Act*, H.R. Rep. No. 116-660, at 5 (Dec. 17, 2020) (citing the HHS OIG report "that identified significant deficiencies in the quality of care delivered to Medicare hospice enrollees").

43. Consequently, in 2020, Congress added Section 1822 to the Social Security Act to establish a scheme of hospice surveys and enforcement remedies to ensure providers were

[13] *See* HHS OIG, *Hospice Deficiencies Pose Risks to Medicare Beneficiarie*s, OEI-02-17-00020 (July 2019), available at https://oig.hhs.gov/documents/evaluation/2677/OEI-02-17-00020-Complete%20Report.pdf (last visited Jan. 15, 2025).
[14] *See id.*, at 2, 4, 15.
[15] *See id.*, at 15.
[16] *See id.* at 17-20.

complying with the requirements of the Medicare program. *See* Consolidated Appropriations Act of 2021, Pub. L. 116-260, § 407, 134 Stat. 1182, 3003 (Dec. 27, 2020).

44. In Section 1822(a), Congress directed that "[a]ny entity that is certified as a hospice program (as defined in section 1395x(dd)(2) of this title) shall be subject to a standard survey by an appropriate State or local survey agency, or an approved accreditation agency, as determined by the Secretary, not less frequently than once every 36 months." 42 U.S.C. § 1395i-6(a)(1).

45. In Section 1822(b), Congress sought to implement an enhanced enforcement program for hospices that were not in compliance with Medicare requirements—the Hospice Special Focus Program. *See* 42 U.S.C. § 1395i-6(b). To that end, Congress directed CMS to "conduct a special focus program for enforcement of requirements for hospice programs that the Secretary has identified as having ***substantially failed to meet applicable requirements*** of [Title 42, Chapter 7 of the U.S. Code]." 42 U.S.C. § 1395i-6(b)(1) (emphasis added). Congress also directed that, "[u]nder such special focus program, the Secretary shall conduct surveys of each hospice program in the special focus program not less than once every 6 months." *Id.* § 1395i-6(b)(2).

46. Thus, by plain statutory text, CMS must identify hospices for the Hospice Special Focus Program based on their record of compliance with the statutory Medicare requirements, which include the regulatory conditions of participation, and then subject those hospices to increased oversight.

47. The legislative history of the Special Focus Program provisions confirms that Congress intended that the Special Focus Program would select hospices based on their records of deficiencies in complying with Medicare requirements. The relevant House

Committee Report describes the Special Focus Program as targeting "hospice agencies that the Secretary identifies as having *substantially failed to meet certification requirements*." *See* H.R. Rep. 116-660, at 9 (emphasis added).

48. Consistent with Congress' focus on Medicare requirements, Section 1822(c) directs CMS to take enforcement action against a hospice "if the Secretary determines on the basis of a standard survey or otherwise that a hospice program that is certified for participation under this subchapter is no longer in compliance with the requirements specified in section 1395x(dd) of this title." 42 U.S.C. § 1395i-6(c). Section 1395i-6(c) authorizes, among other remedies, "penalties in an amount not to exceed $10,000 for each day of noncompliance by a hospice program with the requirements specified in section 1395x(dd) of this title." 42 U.S.C. § 1395i-6(c)(5)(B)(i).

49. In short, Congress enacted Section 1822 of the Social Security Act in response to a report of widespread non-compliance with Medicare requirements among participating hospice programs. Compliance with Medicare requirements is the touchstone for Section 1822's survey-and-enforcement scheme, including the Hospice Special Focus Program.

C. CMS's Initial Proposed Rule for the Hospice Special Focus Program.

50. In July 2021, CMS issued a proposed rule implementing the Special Focus Program. *See* CMS, *Calendar Year 2022 Home Health Prospective Payment System Proposed Rule*, 86 Fed. Reg. 35,874, 35,974 (July 7, 2021). CMS explained that "Section 1822(b) of the Act requires the Secretary to conduct a Special Focus Program for hospice programs that the Secretary has identified as having substantially failed to meet applicable requirements of the Act." *Id.* at 35,974.

51. The July 2021 proposed rule also recognized that "Sections 1812, 1814, 1822, 1861, 1864, and 1865 of the Act establish requirements for Hospice programs and [] authorize surveys to determine whether they meet the Medicare conditions of participation." *Id.* at 36,009. It further stated that "[t]he Secretary must conduct a special focus program for the enforcement of conditions of participation for hospice programs that the Secretary has identified as having substantially failed to meet applicable requirements for Medicare participation." *Id.* at 36,010.

52. Correspondingly, CMS's proposed rule included criteria for the SFP that were based solely on findings of condition-level deficiencies in surveys. *See id.* at 35,974. The proposed inclusion criteria were "(i) [t]he hospice program is found to be deficient with condition-level findings during two consecutive standard surveys," "(ii) [t]he hospice program is found to be deficient with condition-level findings during two consecutive complaint surveys," or "(iii) [t]he hospice program is found to be deficient with two or more condition level findings during a validation survey." *Id.* at 36,010.

53. In November 2021, CMS declined to finalize the proposed rule. Rather, CMS explained that it intended "to review the public comments received and collaborate with hospice stakeholders to further develop the SFP that was initially proposed." CMS, *Calendar Year 2022 Home Health Prospective Payment System Final Rule*, 86 Fed. Reg. 62,240, 62,372 (Nov. 9, 2021).

D. CMS Hires an Outside Consultant and Convenes a Technical Expert Panel.

54. After declining to finalize its proposed rule, "CMS contracted with Abt Associates, Inc. (Abt), an independent research company, to support the development of the hospice SFP." Abt Associates, *2022 Technical Expert Panel and Stakeholder Listening Sessions:*

Hospice Special Focus Program Summary Report at 3 (April 28, 2023) (hereinafter "Technical Expert Report"), https://shorturl.at/OlIPX (last visited Jan. 15, 2025).

55. "Abt and CMS developed a revised preliminary methodology to identify poor performing hospices" for the Hospice Special Focus Program. *Id.* The revised preliminary methodology is an algorithm by which CMS would select hospices for the Hospice Special Focus Program.

56. Unlike the July 2021 proposed rule, the revised preliminary methodology no longer focused on condition-level deficiencies to select hospices. The revised preliminary methodology instead incorporated "a variety of hospice data sources, including hospice survey data," "Medicare claims data," and "consumer evaluations." *Id.* "[T]he Medicare claims data" (HCI scores) and "consumer evaluations" (CAHPS scores) do not measure a hospice provider's compliance with Medicare requirements. *Id.* Thus, CMS's work with Abt started the agency down the path of breaking with Congress' directive to identify hospices that "substantially fail[] to meet" Medicare requirements for the Hospice Special Focus Program. 42 U.S.C. § 1395i-6(b)(1).

57. Abt convened a Technical Expert Panel to provide feedback on the Hospice Special Focus Program, including the revised preliminary methodology. Technical Expert Report, *supra* at 3, 8. The Technical Expert Panel—composed as it was of nine industry experts—met in October and November 2022. Abt then held additional listening sessions "with groups of stakeholders including industry representatives, accrediting organizations, federal experts, and patient advocates." *Id.* at 3. In April 2023, Apt issued a report to CMS describing its work with the Technical Expert Panel and stakeholders.

E. CMS Proposes the Hospice Special Focus Program Rule and Selection Algorithm.

58. In July 2023, CMS issued a new proposed rule to implement the Special Focus Program. *See* CMS, *Calendar Year 2024 Home Health Prospective Payment System Proposed Rule*, 88 Fed. Reg. 43,654 (Jul. 10, 2023).

59. The July 2023 proposed rule states that "[s]election of hospices for the SFP is made based on the highest aggregate scores based on the algorithm used by CMS." *Id.* at 43,817. CMS proposed an algorithm that takes into account four potential criteria for selecting hospices: (i) condition-level deficiencies over a three-year period, (ii) substantiated complaints over a three-year period, (iii) HCI score, and, when available, (iv) CAHPS index score. *See id.* at 43,758-43,761. CMS would later adopt this algorithm verbatim in the Hospice Special Focus Program Final Rule.

60. Notwithstanding Congress' command to identify hospice providers that substantially fail to meet Medicare requirements, only two of CMS's four criteria relate to Medicare compliance—condition level deficiencies and substantiated complaints. The remaining two criteria—CAHPS and HCI scores—do not measure Medicare compliance at all.

1. Condition-Level Deficiencies and Substantiated Complaints

61. CMS's algorithm counts a hospice program's condition level deficiencies "from the previous 3 consecutive years of data." 88 Fed. Reg. at 43,760. "Hospices are surveyed for compliance with hospice program requirements prior to becoming certified . . . and then at least once every 36 months . . . for recertification." *Id.* at 43,759. A condition-level deficiency "is cited on a survey when a hospice is found to be noncompliant with all or part of a condition of participation (CoP), which is one of the health and safety requirements all

hospices are required to meet to participate in Medicare." *Id.* CMS's condition-level deficiency criterion thus helps measure a hospice program's Medicare compliance.

62. CMS's algorithm counts a hospice provider's "total number of substantiated complaints received against a hospice in the last 3 consecutive years of data before the release of the SFP selection list." *Id.* at 43,760. A patient, caregiver, or hospice staff member may file a complaint at any time, *id.* at 43,760, and hospices also regularly self-report complaints. A complaint triggers an investigation into whether the allegations are true and whether they amount to a deficiency in compliance with Medicare requirements. "If the allegation is found to be substantiated or confirmed, the [state agency] informs the hospice and submits the findings." *Id.* Substantiated complaints, too, relate to a hospice's compliance with Medicare requirements.

63. Although condition-level deficiencies and substantiated complaints measure Medicare compliance, CMS implemented these criteria in an unreasonable way. The revised preliminary methodology that CMS developed with Abt scaled these criteria, with limited exceptions, "per 100 beneficiaries served." Technical Expert Report, *supra* at 14. CMS's consultant explained that the scaling "was to ensure that larger hospices were not at a disadvantage compared to smaller hospices." *Id.*

64. Rather than scale these criteria, CMS elected to count hospice providers' *absolute* number of condition level deficiencies and substantiated complaints. As a result, a hospice provider serving 2,000 beneficiaries per year with 4 substantiated complaints would score worse in CMS's algorithm than a hospice provider serving 100 beneficiaries per year with 3 substantiated complaints.

65. Finally, during the rulemaking process, CMS failed to provide hospice providers and other stakeholders with an opportunity to assess the accuracy of its data related to condition-level deficiencies and substantiated complaints. CMS did not publish Excel files with its identification of condition-level deficiencies and substantiated complaints until after the comment period for the Hospice Special Focus Program Final Rule closed.[17] Hospices therefore had no meaningful opportunity to comment on CMS's data collection methods related to condition-level deficiencies and substantiated complaints during the rulemaking process.

66. Moreover, the data related to condition-level deficiencies and substantiated complaint records available to hospice providers and other stakeholders on a CMS website during the rulemaking process was, and continues to be, inaccurate.

2. Hospice Patient Experience Indicator (CAHPS Survey)

67. CMS's CAHPS survey program is used by CMS to calculate quality and patient experience measures. The CAHPS survey program asks hospice patients and caregivers to rate their experiences with certain aspects of their care.[18] Using the survey responses, CMS calculates certain measures, such as "Willing to recommend this hospice," "Getting timely help," and "Training family to care for patient."[19]

68. The CAHPS consumer evaluations do not track compliance with Medicare requirements. They measure "aspects of quality that are *not* found in the [Medicare] survey."

[17] Ex. 2, Declaration of Judith Lund Person, ¶¶ 43-44 (hereinafter "Lund Person Decl.").
[18] *See* CMS, CAHPS Hospice Survey, https://www.cms.gov/data-research/research/consumer-assessment-healthcare-providers-systems/cahps-hospice (last modified Sept. 10, 2024) (last visited Jan. 15, 2025).
[19] *See* CMS, CAHPS Hospice Survey, https://www.cms.gov/medicare/quality/hospice/cahpsr-hospice-survey (last modified Sept. 10, 2024) (last visited Jan. 15, 2025).

88 Fed. Reg. at 77,805 (emphasis added). A hospice need not obtain a certain score on the CAHPS measures as a Medicare requirement. *See* 42 C.F.R. § 418.312.

69. About half of hospices do not report CAHPS scores. 88 Fed. Reg. at 43,761. CMS does require hospices with 50 or more patients to submit CAHPS data, but not as a condition of participation. Hospices with less than 50 patients are exempt from this requirement, *see* 42 C.F.R. § 418.312(e), as are certain newly enrolled hospices.[20] Failure to report CAHPS data has no impact on a hospice's Medicare certification and results only in a minor payment reduction.[21]

70. CMS's algorithm for the Special Focus Program nonetheless includes the following CAHPS measures in a CAHPS index score: (1) Help for Pain and Symptoms, (2) Getting Timely Help, (3) Willingness to Recommend this Hospice, and (4) Overall Rating of this Hospice. *Id.* at 43,760-61.

71. For the approximately 50% of hospices that report CAHPS measures, those measures are weighted *two times* more than the other indicators in the Special Focus Program algorithm, despite being unrelated to the Medicare certification requirements that Congress instructed CMS to enforce. *Id.* at 43,763. For hospices that are exempt from CAHPS requirements or simply failed to report CAHPS measures, the algorithm calculates the hospice's score based only on condition-level deficiencies, substantiated complaints, and HCI score.

[20] *See* CMS, CAHPS Hospice Survey, https://www.cms.gov/medicare/quality/hospice/cahpsr-hospice-survey (last modified Sept. 10, 2024) (last visited Jan. 15, 2025).
[21] *See* CMS, Hospice Quality Reporting Program, https://www.cms.gov/medicare/quality/hospice (last modified Sept. 10, 2024) (last visited Jan. 15, 2025) (providing a 4% payment reduction).

72. Setting aside that using CAHPS scores at all was unlawful because such consumer-evaluation scores do not measure Medicare compliance, this is another area where CMS broke from the revised preliminary methodology that it developed with Abt. The revised preliminary methodology weighted CAHPS scores *half as much* as condition level deficiencies and substantiated complaints, and *a fourth as much* as HCI scores. Technical Expert Report, *supra* at 14. The revised preliminary methodology gave less weight to CAHPS scores because of the large number of hospice providers that do not report CAHPS information. *Id.*

73. Likewise, the Technical Expert Panel expressed "mixed opinions" about increasing the weighting for CAHPS scores due to the lack of availability of CAHPS data. *See id*. at 15-16.

74. Since hospices with less than 50 patients are exempt from reporting CAHPS scores, the algorithm skews arbitrarily toward larger agencies, despite there being no reasonable basis to find that larger agencies are more likely than smaller agencies to fail CMS requirements. CAHPS scores are known to often be lower among providers serving underserved communities, with the result that including CAHPS scores in the SFP algorithm disproportionately targets those providers. *See* 88 Fed. Reg. at 77,805 (Nov. 13, 2023).

75. Finally, in the July 2023 proposed rule, CMS referenced its "analysis of CYs . . . 2019 to 2021 CAHPS Hospice Survey data" and discussed how that analysis impacted its decision about how to treat the CAHPS score in the Special Focus Program algorithm, with a particular focus on how to treat hospices that did not report a CAHPS score. 88 Fed. Reg. at 43,761. CMS failed to provide commenters with access to these above-referenced analyses—omitting critical material used to develop the Special Focus Program algorithm—

thereby denying them a meaningful opportunity to comment on the Special Focus Program Proposed Rule.

3. Hospice Care Index ("HCI")

76. CMS's algorithm also uses a second quality measure that has no grounding in Medicare requirements: the Hospice Care Index ("HCI").[22]

77. HCI is a single number calculated using data from the claims for payment that a hospice has submitted to Medicare taking into account these ten aspects:

a. Continuous Home Care (CHC) or General Inpatient (GIP) Provided

b. Gaps in Skilled Nursing Visits

c. Early Live Discharges

d. Late Live Discharges

e. Burdensome Transitions (Type 1) – Live Discharges from Hospice Followed by Hospitalization and Subsequent Hospice Readmission

f. Burdensome Transitions (Type 2) – Live Discharges from Hospice Followed by Hospitalization with the Patient Dying in the Hospital

g. Per-beneficiary Medicare Spending

h. Skilled Nursing Care Minutes per Routine Home Care (RHC) Day

i. Skilled Nursing Minutes on Weekends

j. Visits Near Death

78. Like the CAHPS score, the HCI score does not measure a hospice's compliance with Medicare's statutory requirements or the regulatory conditions of participation. *Cf.* 42

[22] *See* CMS.gov, Current Measures, https://www.cms.gov/medicare/quality/hospice/current-measures (last modified Sept. 10, 2024) (last visited Jan. 15, 2025).

U.S.C. § 1395x(dd); 42 C.F.R. §§ 418.20-.116. A hospice need not obtain a certain score on the HCI measure to remain Medicare compliant.

79. In fact, HCI scores are not available for over 20% of hospices, especially those that are smaller or new.[23] Despite that enormous gap in data, CMS persisted in using HCI as an input and arbitrarily assigned the average HCI score to hospices that did not have a publicly reported HCI score. *See* 88 Fed. Reg. at 43,762. As a result, a hospice that has a record of serious deficiencies in complying with Medicare requirements—*i.e.*, a true "poor performer"—but that lacks an HCI score receives an artificial and arbitrary bump up to the average HCI score in CMS's algorithm.

F. Commenters Raise Serious Concerns about CMS's Algorithm for Selecting Hospices.

80. CMS received numerous comments on the proposed rule, including from national trade associations. Commenters raised serious concerns about CMS's algorithm for selecting hospice programs, among them CMS's failure to scale condition-level deficiencies and substantiated complaints by beneficiaries served, CMS's assignment of average HCI scores to hospices with missing HCI data, and CMS's double weighting of CAHPS scores.

81. For example, on August 16, 2023, the National Hospice and Palliative Care Organization, the National Association for Home Care and Hospice, the National Partnership for Healthcare and Hospice Innovation, and Leading Age submitted comments on CMS's July 2023 proposed rule.[24] These national associations explained that the Technical

[23] *See* 88 Fed. Reg. at 77,807 (Nov. 13, 2023) ("[A]pproximately 21 percent of hospices did not have a publicly reported HCI score. Hospice providers that do not have HCI scores are likely to be small . . . [or] new . . . or both.").

[24] Comments of the National Association for Home Care and Hospice, and the National Partnership for Healthcare, Hospice Innovation, and Leading Age, Docket ID CMS-2023-0113-0180 (Aug. 16, 2023).

Expert Panel scaling of condition-level deficiencies and substantiated complaints "was to ensure that larger hospices were not at a disadvantage compared to smaller hospices," and "scaling the data is essential to ensure programs are comparable."[25] "If the goal is to ensure beneficiaries are receiving patient-centered, quality hospice care," the national associations concluded, "it is necessary to review these data as ratios rather than raw numbers."[26]

82. The national associations also raised concerns about the missingness of HCI data for 21.7% of hospices. Based on their analysis, the national associations "found providers without HCI scores were less likely to be included in the 10th percentile and, therefore, less likely to be included in the SFP," and "hospices that did not have an HCI score *had dramatically more CLDs per beneficiary* yet were less likely to fall into the bottom 10% of hospices."[27] "Thus, hospices more deserving of the SFP were less likely to be included."[28]

83. The national associations identified that "there are major limitations with the existing CAHPS® Hospice Survey data that . . . need to be addressed before CAHPS is incorporated into the algorithm."[29] Given that CMS had double weighted CAHPS scores and 49% of hospices do not report CAHPS data, the national associations raised concerns that CMS's proposed CAHPS selection criteria "will distort SFP selection."[30]

84. On October 4, 2023, a bipartisan group of Congress members raised similar concerns with CMS by letter.[31] The letter identified the lack of scaling condition-level

[25] *Id.* at 1-2.
[26] *Id.* at 2.
[27] *Id.* at 2 (emphasis added).
[28] *Id.*
[29] *Id.*
[30] *Id.*
[31] Letter from Beth Van Duyne, Member, United States House of Representatives, et al. to Shalanda Young, Director, Office of Management and Budget, and Chiquita Brooks-LaSure, Administrator, CMS (Oct. 4, 2023).

deficiencies and substantiated complaints as problematic. The Congress members stated that "accounting for relative size is critical to ensuring CMS is accurately comparing like hospices to best identify hospices in most need of focused education and oversight."[32]

85. The letter continued that "we are concerned that the proposal relies too heavily on the Hospice Care Index (HCI) and the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey data – both of which have a large proportion of missing publicly reported data."[33] As for double weighting of CAHPS data, the Congress members "request[ed] CMS provide more transparency into why its proposed methodology for CAHPS data differed so drastically from that which the [Technical Expert Panel] recommended."[34]

86. The Congress members closed the letter by requesting that CMS engage in additional analysis before finalizing the July 2023 proposed rule. The letter states, "We request that CMS, in consultation with the [Technical Expert Panel], address the aforementioned limitations, and provide opportunity for stakeholder input on the changes prior to finalizing the SFP."[35]

G. CMS Finalizes the Hospice Special Focus Program Rule.

87. In November 2023, CMS finalized the proposed rule—the Hospice Special Focus Program Final Rule. *See* 88 Fed. Reg. at 77,676 (Nov. 13, 2023). The Hospice Special Focus Program Final Rule went into effect on January 1, 2024.

88. In the Final Rule, CMS defined the Hospice Special Focus Program as "a program conducted by CMS to identify hospices as poor performers, based on defined quality

[32] *Id.* at 1.
[33] *Id.* at 2.
[34] *Id.*
[35] *Id.*

indicators, in which CMS selects hospices for increased oversight to ensure that they meet Medicare requirements." 42 C.F.R. § 488.1105.

89. Hospices are selected for the Special Focus Program "based on the highest aggregate scores based on the algorithm used by CMS." 42 C.F.R. § 488.1135(b)(1).

90. The Final Rule calls for CMS to publicly post on its website (1) the 10 percent of hospice programs with the highest aggregate scores as determined by the CMS Special Focus Program algorithm and (2) the hospices that were selected from that 10 percent for participation in the Special Focus Program. 42 C.F.R. § 488.1135(f).

91. In the Final Rule, CMS adopted the same unlawful algorithm that had been proposed in the July 2023 proposed rule. 88 Fed. Reg. at 77,804. The Final Rule's algorithm thus calls for CMS to identify hospices for the Hospice Special Focus Program with condition-level deficiencies, substantiated complaints, CAHPS scores, and HCI scores. *Id.* And CMS considers only condition-level deficiencies, substantiated complaints, and HCI scores for the roughly half of hospices that do not report CAHPS information. *Id.* Thus, CMS finalized its unlawful approach of identifying hospices with CAHPS and HCI scores rather than based on Medicare program compliance.

92. In addition to disregarding CMS's statutory mandate, the algorithm continues to bear the same serious and arbitrary flaws as the July 2023 proposed rule. It does not scale condition-level deficiencies or substantiated complaints by beneficiaries served; it double weighs CAHPS scores when available; and it assigns average HCI scores for the approximately 21% of hospices that do not have HCI scores available. 88 Fed. Reg. at 77,804 (double weighting CAHPS), 77,808 (averaging missing HCI scores), 77,809 (refusing to scale).

93. Selection for the Special Focus Program carries serious legal consequences in addition to the irreparable harms attendant on being publicly deemed a "poor performer." If selected for the Special Focus Program, a hospice is surveyed not less than once every 6 months rather than on the standard 36-month cycle. *Compare* 42 C.F.R. § 488.1135(c)(1), *with* 42 C.F.R. § 488.1110(a).

94. If selected for the Special Focus Program, a hospice program whose Medicare certification is based upon accreditation immediately loses its deemed status and is placed under CMS or State survey agency jurisdiction until completion of the SFP (or termination). 42 C.F.R. § 488.1135(b)(2).

95. A hospice is deemed to have "completed" the Special Focus Program when it has either (a) completed two surveys within 18 months with no condition-level deficiencies and has no pending complaint surveys or (b) returned to substantial compliance with all requirements. 42 C.F.R. § 488.1135(d). A hospice that does not "complete" the Special Focus Program will be considered for termination from the Medicare program. 42 C.F.R. § 488.1135(e).

H. CMS Fails to Confront the Serious Flaws in the Hospice Special Focus Program Final Rule.

96. CMS's algorithm for identifying hospices is unlawful because it relies on criteria that do not measure Medicare compliance—CAHPS and HCI scores. This approach exceeds CMS's statutory authority. It is also arbitrary and capricious: An agency may not rely on factors that Congress did not intend for it to consider. The Hospice Special Focus Program is therefore fundamentally flawed and must be set aside.

97. CMS also failed to articulate reasonable explanations for the most serious flaws in the algorithm: (1) relying on CAHPS and HCI scores, (2) failing to scale condition-level

deficiencies and substantiated complaints, and (3) assigning average HCI scores to hospices with missing HCI data.[36]

1. Reliance on CAHPS and HCI Scores.

98. Section 1395i-6(b)(1) makes identifying hospice providers that have "substantially failed to meet applicable [Medicare] requirements" the touchstone of the Hospice Special Focus Program. CMS has provided no explanation for how CAHPS and HCI scores are consistent with Congress' directive, and indeed they are not. This was a major aspect of the problem that called for an explanation.

99. Indeed, before CMS published the July 2023 proposed rule, the Technical Expert Panel report commissioned by CMS had found that using CAHPS and HCI scores resulted in identifying hospices that "did not have a high number of substantiated complaints and Quality of Care CLDs," which "point[ed] to a *lack of correlation* across these dimensions." Technical Expert Report, *supra* at 15 (emphasis added). That is, the evidence submitted to CMS was that CAHPS and HCI scores are not proxies for hospices that fail to comply with Medicare requirements. Given the statutory text, comments, and evidence, CMS acted unreasonably when it failed to explain (and cannot explain) how CAHPS and HCI scores, by their nature or effect, identify a substantial failure to comply with Medicare requirements.

2. Refusal to Scale Condition-Level Deficiencies and Substantiated Complaints.

100. "Many commenters" raised concerns with CMS's decision to not scale condition-level deficiencies and substantiated complaints. 88 Fed. Reg at 77,808. In

[36] As for the double weighting of CAHPS scores, CMS claims that its initial analysis shows its "approach does not significantly help or hurt providers with or without CAHPS Hospice Survey data" in terms of overall algorithm scores. 88 Fed. Reg. at 77,805. CMS has not released its initial analysis; Plaintiffs reserve the right to amend once CMS files the administrative record.

response, CMS claimed that according to its undisclosed testing of the algorithm, "there was not a linear relationship between the number of CLDs identified in hospice surveys and the average number of beneficiaries that a CLD provider served each year," and that all providers have the same opportunity to receive condition-level deficiencies. *Id.* The lack of linear relationship would also occur if, as commenters have suggested, larger hospice providers generally have higher rates of compliance with Medicare requirements. CMS's conclusory response based on its undisclosed data was insufficient.

101. As for substantiated complaints, CMS acknowledged that "large hospices have more opportunities to receive complaints than small hospices." *Id.* But CMS rejected scaling because "this does not change the opportunity for substantiation (that is, a complaint cannot be substantiated if the surveyor does not find evidence that supports the complaint)." *Id.* This explanation is plainly inadequate; it is a truism that any given complaint can be substantiated or not. CMS left the fundamental issue unaddressed: Whether a hospice program's absolute number of substantiated complaints reflects a worse record of substantial compliance with Medicare requirements relative to other hospices.

102. CMS's failure to grapple with the relationship between absolute numbers and compliance leaves yet another major problem unaddressed. CMS's algorithm purports to identify the poorest performing hospices, and CMS purports to include the 50 poorest performing providers across the entire country in the Special Focus Program. 88 Fed. Reg. at 77,799, 77,809. Any serious flaw in the selection criteria comes at a cost. Because the selection is *relative*, based on overall algorithm scores, flaws in the selection criteria prevent CMS from identifying the worst performing hospices for the Special Focus Program, while misleading Medicare beneficiaries about which hospices are poor performers and wasting

resources on increased oversight for providers that do not need it. CMS has willingly tolerated bias in its algorithm, such as skewing toward large providers that serve many beneficiaries per year, but failed to offer a reasoned explanation for doing so, given it prevents CMS from identifying the worst performing hospices for the Special Focus Program.

3. Assigning Average HCI Scores to Hospices with Missing HCI Data.

103. In response to commenter concerns about missing HCI scores, CMS acknowledged that approximately 21% of hospices did not report HCI scores. 88 Fed. Reg. at 77,807. CMS also admitted that "hospice providers that did not have a publicly reported HCI score were significantly less likely to be identified in the candidate list of the SFP," and that "[t]his suggests that the algorithm may be limited in its ability to identify poor performing hospices with under 20 discharges over two years." *Id.* CMS nonetheless concluded that "the benefits of using the HCI score, including that it is based on claims data, that it captures care processes occurring at a hospice, and that it has no additional data reporting burden, outweigh the concerns." *Id.*

104. Here, again, CMS failed to offer a reasoned explanation for tolerating admitted bias in its algorithm. The cost is not error in the abstract as CMS portrays it. By its own admission, CMS's flawed HCI metric will likely leave poor performing small hospices out of the Special Focus Program and, as a corollary, put better performing larger hospice providers in the Program. This works unnecessary reputational harm, misinforms Medicare beneficiaries about provider quality, and wastes oversight resources. Yet CMS's explanation fails to account for these serious downsides.

I. The December 2024–January 2025 Hospice Special Focus Program List

105. On or about December 18, 2024, Defendants notified by letter some 50 hospice agencies that they would be included in the Special Focus Program. CMS offered no procedures for these agencies to correct errors in CMS's data related to their hospices or to challenge their designation. Indeed, the notification letters stated that their "selection for the SFP cannot be appealed."[37]

106. On December 20, 2024, Defendants published on the CMS website the first Hospice Special Focus Program List that included "the list of the initial cohort of 50 hospices selected for participation" in the SFP in 2025.[38] Together with this Hospice Special Focus Program List, CMS purported to release its "underlying data" that was used to create the list and that would be used to identify "future SFP candidates."[39]

107. The Hospice Special Focus Program List implements the unlawful algorithm from the Hospice Special Focus Program Final Rule. That is clear from, among other things, guidance that CMS published alongside the List.[40]

108. On or around January 2, 2025, CMS removed the Hospice Special Focus Program List from its website and replaced it with a new version.[41] CMS noted that it was making "technical corrections and changes" and would provide an update shortly.[42] The revised Hospice Special Focus Program List removed three hospice programs.[43]

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[37] Ex. 1, Declaration of Houston Hospice, ¶ 6 & Ex. A.
[38] See Hospice Special Focus List, available at https://www.cms.gov/medicare/health-safety-standards/certification-compliance/hospice-special-focus-program (last visited Jan. 15, 2025).
[39] See Hospice Special Focus List, available at https://www.cms.gov/medicare/health-safety-standards/certification-compliance/hospice-special-focus-program (last visited Jan. 15, 2025).
[40] *See generally* CMS, Hospice Special Focus Program User's Guide: *Algorithm and Public Reporting* (Dec. 2024), https://shorturl.at/T6v7p (last visited Jan. 15, 2025).
[41] Ex. 2, Lund Person Decl., ¶ 45.
[42] *Id.*
[43] *Id.*

109. On or around January 8, 2024, CMS posted another revised Hospice Special Focus Program List that identifies 50 hospice providers for the Hospice Special Focus Program.[44] The Hospice Special Focus Program List dated January 8, 2024 includes four hospice programs that were not originally included in the December 20, 2024 version, while removing four hospice programs that were originally included.[45]

110. The Hospice Special Focus Program List currently includes six hospice providers, including members of the Association Plaintiffs, with ***no*** condition level deficiencies or substantiated complaints in the last three years.[46] In other words, six hospice providers in the Special Focus Program remained substantially compliant with Medicare requirements throughout the period covered. The fact that 12% of the hospices in the Special Focus Program have track records of unbroken substantial compliance with Medicare, by CMS's chosen metrics, underscores the arbitrary nature of CMS's approach.

111. The Hospice Special Focus Program List does not include the top 50 scoring hospices according to CMS's algorithm.[47] The Final Rule states that "[s]election of hospices for the SFP is made based on the *highest aggregate scores* based on the algorithm used by CMS." 42 C.F.R. § 488.1135(b)(1) (emphasis added). When "[s]everal commenters questioned how CMS will use discretion to select hospice programs for the SFP from a list of 10 percent of highest scoring hospices," CMS responded that it would "select *the poorest performing hospices*, from the 10 percent selectee list based on the finalized SFP algorithm score, in *sequential value*." 88 Fed. Reg. at 77,809 (emphasis added)

[44] Ex. 2, Lund Person Decl., ¶ 46.
[45] *Id.*
[46] Ex. 2, Lund Person Decl., ¶ 23; Ex. 3, Hammon Decl., ¶ 8.
[47] Ex. 2, Lund Person Decl., ¶ 25.

112. Rather than include the top-50 scoring hospices, as the Final Rule requires, CMS has arbitrarily chosen a group of 50 hospices from a much larger range of scores, up to the top-121 scoring hospices.[48] In effect, CMS has selected 31 hospice providers in the Special Focus Program List that are not within the top 50 according to CMS's algorithm.[49] For example, Plaintiff Houston Hospice's algorithm score ranks 118th, yet CMS selected it for the Special Focus Program.[50] At the same time, CMS passed over 71 higher-scoring hospices and did not include them on the Special Focus List, despite their having higher algorithm scores than the List's lowest-scoring hospice on the List.[51]

113. CMS has not explained what criteria or methodology it actually used to select the hospices for the Special Focus List. CMS has either disregarded the Final Rule, which called for selection of the highest scoring providers, or CMS has erred in applying its algorithm. Either way, the Hospice Special Focus Program List is arbitrary and capricious.

114. The Hospice Special Focus Program List is also arbitrary and capricious because CMS made demonstrable errors in assigning complaints to hospice providers.[52] In connection with the Hospice Special Focus Program List, CMS published an Excel file with substantiated complaints used in its algorithm.[53] The Excel file includes, among other things, whether a state agency performed the survey leading to a substantiated complaint and identifying information such as "Complaint ID" and "Survey Event ID."

115. Certain state agencies, such as the California Department of Public Health and the Florida Agency for Health Care Administration, make their complaint files publicly

[48] Ex. 2, Lund Person Decl., ¶ 25.
[49] *Id.*
[50] *Id.*
[51] *Id.*
[52] Ex. 2, Lund Person Decl., ¶ 29, 33.
[53] *Id.*, ¶ 29.

available.[54] If CMS has accurately collected and analyzed data, CMS's Excel file of substantiated complaints should match the public records from the state agencies who performed the surveys.[55]

116. Based on a comparison of public records, however, CMS appears to have made errors in identifying substantiated complaints.[56] For example, CMS has listed Complaint ID No. 90822 alleged against provider Elizabeth Hospice as "substantiated."[57] The corresponding State survey from California for the complaint shows a finding that, "NO DEFICIENCIES WERE IDENTIFIED FROM THIS SURVEY."[58] The complaint was not, in other words, substantiated.

117. Similarly, CMS has listed Complaint ID Nos. 88846, 88848, and 88850 alleged against provider Sharp Hospicecare for which the State of California conducted surveys on May 19, 2022, November 22, 2021, and July 28, 2022, respectively, as "substantiated."[59] A review of the State surveys for these complaints shows a finding that "NO DEFICIENCIES WERE IDENTIFIED FROM THIS SURVEY."[60] These complaints, too, were not substantiated.

118. For another example, CMS has identified Complaint ID No. 83984 alleged against provider Lifepath Hospice for which the State of Florida conducted a survey on June 4, 2021 as "substantiated."[61] But a review of the State survey for that complaint shows

[54] Ex. 2, Lund Person Decl., ¶ 30.
[55] Ex. 2, Lund Person Decl., ¶¶ 30-32.
[56] Ex. 2, Lund Person Decl., ¶¶ 33.
[57] *Id.*, ¶ 34.
[58] *Id.*
[59] Ex. 2, Lund Person Decl., ¶¶ 35.
[60] *Id.*
[61] Ex. 2, Lund Person Decl., ¶ 36.

a finding that, "The agency was in compliance with Code of Federal Regulations (CFR) 42 Part 418, Condition of Participation for Hospice Care."[62]

119. There appear to be other errors in CMS's application of the substantiated complaint criteria. According to its guidance document, CMS claimed it would only count complaints as substantiated if the Complaint ID on CMS Form 2567 matches the Complaint ID in its Excel file of substantiated complaints.[63] CMS also claimed that complaints related to state licensure issues, whether substantiated or unsubstantiated, would not be counted for purposes of its algorithm.[64] On multiple occasions, though, CMS appears to have counted complaints as substantiated when the Complaint IDs did not match or when the underlying complaint related only to a state licensure issue.[65]

120. In implementing the Final Rule through the Hospice Special Focus Program List, CMS has provided no opportunity to challenge the substantiated complaints identified in its Excel file that factor into its algorithm, either before or after publishing the List. Had CMS provided an opportunity for hospices to be heard, CMS could have avoided errors in the List and spared hospices unnecessary harm.

121. Because CMS made clear errors in applying the algorithm, the Hospice Special Focus Program List lacks the support of substantial evidence, is arbitrary and capricious, and should be set aside.

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[62] *Id.*
[63] CMS, Hospice Special Focus Program User's Guide: *Algorithm and Public Reporting* at 8, https://shorturl.at/T6v7p (last visited Jan. 15, 2025).
[64] *Id.*
[65] Ex. 2, Lund Person Decl., ¶¶ 37-38.

J. Defendants' Unlawful Actions Have Caused and Will Continue to Cause Irreparable Harm to Houston Hospice.

122. Houston Hospice was one of the providers that received a letter from CMS on December 18, 2024.[66] The letter informed Houston Hospice that its "hospice program has been selected for the Special Focus Program (SFP) (42 C.F.R. § 488.1135) based on the SFP selection methodology," and that Houston Hospice "will be under enhanced oversight."[67] CMS made clear that "[y]our selection for the SFP cannot be appealed."[68]

123. On December 20, 2024, CMS published on its website the Special Focus Program List that included Houston Hospice. Houston Hospice had no opportunity to rebut or even discuss CMS's damaging claims before the agency posted Houston Hospice's name on the Special Focus Program list.[69]

124. Houston Hospice has suffered and will continue to suffer irreparable harm from its unlawful inclusion in the Hospice Special Focus Program.

1. <u>CMS Has Harmed Houston Hospice's Reputation.</u>

125. CMS defines the Special Focus Program as "a program conducted by CMS to identify hospices as poor performers, based on defined quality indicators, in which CMS selects hospices for increased oversight to ensure that they meet Medicare requirements." 42 C.F.R. § 488.1105. By including Houston Hospice in the Special Focus Program, CMS has publicly labelled Houston Hospice a "poor performer" among all hospice providers in the country and has implied that Houston Hospice does not "meet Medicare requirements."

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[66] Ex. 1, Houston Hospice Decl., ¶ 6 & Ex. A.
[67] Ex. A to Ex. 1, Houston Hospice Decl. Houston Hospice received the letter that is Exhibit A as a Microsoft Word file, with the "Formatted" comment in the margin.
[68] *Id.*
[69] Ex. 1, Houston Hospice Decl., ¶ 6.

126. That is simply not the case. Houston Hospice is the oldest and largest nonprofit hospice in Houston.[70] Since 1980, Houston Hospice has provided uncompromising, compassionate, end-of-life care to patients and families across Texas.[71] Houston Hospice is committed to providing the highest quality hospice care for patients of all ages, races, ethnicities, and places of origin—regardless of whether these individuals have insurance.[72]

127. The communities Houston Hospice serves believe it is accomplishing its mission.[73] According to the most current Consumer Assessment of Healthcare Providers and Systems survey data for January 2025, 100% of families responding to the survey would recommend Houston Hospice.[74] Houston Hospice is also accredited by the National Institute for Jewish Hospice and was named "Hospice of Choice" by Houston Jewish Funerals, Distinctive Life Cremation and Funeral Services.[75] The Mayor of Houston recognized Houston Hospice's "compassionate and respectful physical, social and spiritual support to [its] patients, loved ones and caregivers" in a proclamation declaring November 18, 2014 as "Houston Hospice Day."[76] Houston Hospice was awarded the 2017 Readers' Choice Award for Best Hospice (Houston Area).[77]

128. Houston Hospice has long been committed to compliance with all laws and regulations, including the Medicare conditions of participation.[78] Houston Hospice has a robust and exemplary compliance program.[79] It has been accredited by Community Health

[70] Ex. 1, Houston Hospice Decl., ¶ 9.
[71] *Id.*
[72] *Id.*
[73] Ex. 1, Houston Hospice Decl., ¶ 11.
[74] *Id.*, ¶ 12.
[75] *Id.*
[76] *Id.*, ¶ 11.
[77] *Id.*, ¶ 12.
[78] Ex. 1, Houston Hospice Decl., ¶ 10.
[79] *Id.*, ¶¶ 10, 13-14 (describing Houston Hospice's compliance program).

Accreditation Partner (CHAP) since 2008.[80] In February 2024, Houston Hospice underwent its reaccreditation survey and was found to be in substantial compliance with all Medicare conditions of participation.[81] Placing Houston Hospice on a list purporting to identify the nation's hospices with the poorest records of Medicare compliance is misleading and wrong.[82]

129. CMS's public criticism has caused and will continue to cause harm. Houston Hospice must attract Medicare beneficiaries to its hospice program.[83] Because Texas is not a certificate-of-need state, patients have a large number of hospice programs from which to choose.[84] In fact, there are 231 Medicare-certified hospice programs operating in Harris County alone, and 343 Medicare-certified hospice programs within Houston Hospice's 13-county geographic footprint.[85] CMS's public criticism will deter patients from selecting Houston Hospice.[86] Competitors will use the listing against Houston Hospice as a way to deter referral sources from offering Houston Hospice as a reputable option for care.[87]

130. CMS's public criticism will also likely do substantial damage to Houston Hospice's ability to obtain both the charitable contributions and the volunteer assistance that is critical to Houston Hospital's survival.[88] As a non-profit, Houston Hospice is highly dependent on the generosity of its community, generosity expressed through contributions of both finances and time.[89] The reimbursements that Houston Hospice receives from Medicare

[80] *Id.*, ¶ 13.
[81] *Id.*
[82] *Id.*
[83] Ex. 1, Houston Hospice Decl., ¶ 17.
[84] *Id.*
[85] *Id.*
[86] *Id.*
[87] *Id.*
[88] Ex. 1, Houston Hospice Decl., ¶ 18.
[89] *Id.*

and other payors is insufficient to cover its expenses to provide high quality care.[90] Houston Hospice would operate at a significant deficit but for the community's generous contributions, which accounted for 13% of its annual revenue in 2023.[91] The negative publicity and reputational harm associated with CMS's public criticism will likely harm Houston Hospice's ability to obtain the charitable contributions necessary for its success.[92]

131. Houston Hospice is also proud of the substantial volunteer commitment to its program.[93] Houston Hospice had 101 volunteers help support patients and their families in 2024, accounting for 5,215 total volunteer hours and over $150,000 of cost savings.[94] CMS's actions will make it harder to recruit and sustain volunteers, who may question whether they want to give their time to, and be associated with, Houston Hospice.[95]

132. CMS regulations require Houston Hospice to utilize volunteers in addition to its paid workforce. 42 C.F.R. § 418.78. In 2024, volunteer hours made up 7% of Houston Hospice's total hours, and 5.6% for Medicare-approved hours.[96] Houston Hospice has deep concerns that CMS's actions will serve as a barrier to attracting volunteers, as they may be misled by CMS's listing into believing that Houston Hospice is a poor performer.[97]

133. Houston Hospice also competes with other hospice programs and a significant number of other medical providers for healthcare professionals and staff.[98] The labor market for healthcare providers and other staff has proven challenging over the last several years and

[90] *Id.*
[91] *Id.*
[92] *Id.*
[93] Ex. 1, Houston Hospice Decl., ¶ 19.
[94] *Id.*
[95] *Id.*
[96] Ex. 1, Houston Hospice Decl., ¶ 19.
[97] *Id.*
[98] Ex. 1, Houston Hospice Decl., ¶ 20.

remains so today.[99] CMS's public criticism will make it more difficult for Houston Hospice to compete with other providers (among other potential employers) for healthcare professionals and other staff.[100]

2. CMS Has Imposed Increased Compliance Costs on Houston Hospice.

134. The Hospice Special Focus Program Final Rule requires that hospices in the Special Focus Program be surveyed at least every six months rather than Medicare's standard 36-month period. *Compare* 42 C.F.R. § 488.1110(a), *with id.*, § 488.1135(c)(1). Since becoming accredited by CHAP in 2008, Houston Hospice's reaccreditation surveys have taken place every three years.[101] Houston Hospice's unlawful inclusion in the Special Focus Program will greatly increase the frequency with which it will be surveyed.[102]

135. Houston Hospice incurs compliance costs from each survey.[103] Houston Hospice must comply with surveyors.[104] This involves employees sitting for interviews, providing records, and otherwise working with the surveyors.[105] In general, Houston Hospice devotes roughly 100 employee hours per survey at an average cost of $55 per hour.[106] Each survey therefore imposes approximately $5,500 in compliance costs on Houston Hospice.[107] Because Houston Hospice has been included in the Special Focus Program, Houston Hospice will necessarily incur those compliance costs at least every six months, as opposed to surveys

[99] *Id.*
[100] *Id.*
[101] Ex. 1, Houston Hospice Decl., ¶ 21.
[102] *Id.*
[103] Ex. 1, Houston Hospice Decl., ¶ 21.
[104] *Id.*
[105] *Id.*
[106] *Id.*
[107] *Id.*

every three years as in the past—a significant and unnecessary expenditure of the limited funds available to Houston Hospice.[108]

3. CMS Has Revoked Houston Hospice's Deemed Status.

136. Houston Hospice elected to become accredited by CHAP in 2008 to be held to a high standard of care with expert support.[109] Houston Hospice pays for the expertise of the accrediting agency to ensure high quality care, ongoing education, and compliance with federal and state conditions of participation.[110] Through this process, Houston Hospice also attained deemed status with Medicare accepting CHAP surveys in lieu of its own survey.[111]

137. Houston Hospice has maintained CHAP accreditation and deemed status for the past 16 years.[112] Houston Hospice has now lost the benefit of CHAP accreditation and its deemed status due to being placed in the Special Focus Program.[113] Thus, the value of CHAP accreditation, which cost Houston Hospice $19,600 for the most recent three-year period, has been substantially eroded.[114]

K. Defendants' Unlawful Actions Have Caused and Will Continue to Cause Irreparable Harm to Members of the Association Plaintiffs.

138. The Association Plaintiffs have members who have been included in the Hospice Special Focus Program. As with Houston Hospice, the members of the Association Plaintiffs received from CMS letters informing them of their inclusion in the Special Focus

[108] *Id.*
[109] Ex. 1, Houston Hospice Decl., ¶ 23.
[110] *Id.*
[111] *Id.*
[112] Ex. 1, Houston Hospice Decl., ¶ 23
[113] *Id.*
[114] *Id.*

Program. On December 20, 2024, CMS identified members of the Association Plaintiffs on the Hospice Special Focus Program List.[115]

139. Members of the Association Plaintiffs have suffered and will continue to suffer irreparable injury from the unlawful Hospice Special Focus Program Final Rule and Hospice Special Focus Program List.

140. By including members of the Association Plaintiffs in the Special Focus Program, CMS has publicly labelled those members "poor performers" and implied that they do not "meet Medicare requirements."[116] CMS's public criticism will make it more difficult for those members to attract patients for their Medicare programs, as well as to attract and retain employees.[117] At least some consumers review CMS lists and will not select hospice programs that are included on negative CMS listings when seeking hospice care for themselves or their loved ones.[118]

141. In addition, the reputational harm makes it more difficult for hospice programs to attract referrals from other facilities and makes it less likely other facilities will accept referrals from them, with the latter harming not only the hospice providers but also their patients.[119] At least some referral sources will not refer patients to hospices on CMS lists out of fear that patients will not receive adequate care and that working with a hospice labelled as a "bad actor" could lead to scrutiny of the referral source by state regulators.[120] Hospice providers sometimes transfer patients to nursing homes or hospitals for respite or other

[115] Ex. 3, Hammon Decl., ¶ 8; Ex. 4, Reinhardt Decl., ¶ 11; Ex. 5., AHHC Decl., ¶ 9.
[116] Ex. 3, Hammon Decl., ¶ 10; Ex. 4, Reinhardt Decl., ¶ 13; Ex. 5., AHHC Decl., ¶ 11; Ex. 6, SCHCHA Decl., ¶ 11.
[117] Ex. 3, Hammon Decl., ¶ 10; Reinhardt Decl., ¶ 14; Ex. 5., AHHC Decl., ¶ 11; Ex. 6, SCHCHA Decl., ¶ 11.
[118] Ex. 4, Reinhardt Decl., ¶ 15.
[119] *Id.*, ¶¶ 16-17.
[120] *Id.*, ¶ 16.

specialized care.[121] At least some nursing homes and hospitals will not accept patients from hospices that are included in CMS programs for fear that working with a "bad actor" could invite regulatory scrutiny.[122]

142. CMS's public criticism is misleading. For example, multiple TAHCH members that have been included in the Hospice Special Focus Program have zero condition level deficiencies and zero substantiated complaints over the past three years.[123] Thus, while CMS has told the public, including Medicare beneficiaries, that TAHCH's members are "poor performers" in complying with Medicare requirements and need additional oversight, these members remained fully compliant with Medicare throughout the relevant period according to CMS's own criteria for the Hospice Special Focus Program.

143. CMS has imposed increased compliance costs on members of the Association Plaintiffs through its unlawful actions. Surveys are burdensome for members of the Association Plaintiffs.[124] During a survey, a member must cooperate with the surveyor throughout the intrusive and disruptive survey process.[125] This often involves employees sitting for interviews, providing records, scheduling home visits, and providing any other information that the surveyor might request—all while taking these employees away from time dedicated to direct patient care.[126] Hospice providers also often hire consultants to facilitate and streamline the survey process.[127] Members spend thousands of dollars in

[121] *Id.*, ¶ 17.
[122] *Id.*, ¶ 17.
[123] Ex. 3, Hammon Decl., ¶ 8.
[124] Ex. 3, Hammon Decl., ¶ 12; Ex. 4, Reinhardt Decl., ¶ 20; Ex. 5, AHHC Decl., ¶ 13; Ex. 6, SCHCHA Decl., ¶ 13.
[125] Ex. 3, Hammon Decl., ¶ 12; Ex. 4, Reinhardt Decl., ¶ 20; Ex. 5, AHHC Decl., ¶ 13; Ex. 6, SCHCHA Decl., ¶ 13.
[126] Ex. 3, Hammon Decl., ¶ 12; Ex. 4, Reinhardt Decl., ¶ 20; Ex. 5, AHHC Decl., ¶ 13; Ex. 6, SCHCHA Decl., ¶ 13.
[127] Ex. 4, Reinhard Decl., ¶ 20.

employee time and resources complying with each survey.[128] By including members of the Association Plaintiffs in the Special Focus Program, CMS has increased their survey frequency and, consequently, increased their compliance costs.

144. CMS has also revoked deemed status for members of the Association Plaintiffs. Some members of the Association Plaintiffs previously held deemed status and were subject to surveys from accrediting agencies such as the Community Health Accreditation Partner (CHAP) and the Accreditation Commission for Health Care (ACHC).[129] Hospice programs select deemed status because, for among other reasons, deemed status is often tied to quality metrics used in contracting with insurance companies and other payer sources, allowing the hospice program to obtain favorable rates and referral status.[130] Members who have been placed in the Special Focus Program will lose the benefits of deemed status and will now be subject to surveys from state survey agencies.

145. Members will lose other benefits of deemed status. Deemed status through independent accreditation provides a reputational boost to hospice providers, as accreditation and deemed status are considered above and beyond minimum standards.[131] Accreditation agencies, including ACHC, provide best practices and recommendations to help hospices elevate standard of care.[132] Members that have been included in the unlawful Hospice Special Focus Program will lose these benefits of deemed status.

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[128] Ex. 3, Hammon Decl., ¶ 12; Ex. 4, Reinhardt Decl., ¶ 20; Ex. 5, AHHC Decl., ¶ 13; Ex. 6, SCHCHA Decl., ¶ 13.
[129] Ex. 3, Hammon Decl., ¶ 13; Ex. 4, Reinhardt Decl., ¶ 21; Ex. 5, AHHC Decl., ¶ 14. Additionally, the Joint Commission provides accreditation of many hospices.
[130] Ex. 3, Hammon Decl., ¶ 13; Ex. 5, AHHC Decl., ¶ 14.
[131] Ex. 4, Reinhardt Decl., ¶ 21.
[132] *Id.*, ¶ 21.

146. In addition, CMS has caused irreparable harm to Association Plaintiff members by posting erroneous data about substantiated complaints on its Special Focus List website. As noted, CMS's "underlying data" includes an Excel file titled "Hospice Special Focus Program Substantiated Complaints." CMS's Excel file includes various errors, including complaints that were not substantiated or that related only to state-licensing deficiencies, which are not supposed to count for the SFP algorithm.[133] CMS's public posting of data that purport to show a hospice had a deficiency in Medicare compliance when, in fact, the hospice did not causes inevitable reputational harm to that hospice.

COUNT ONE
Violation of 5 U.S.C. § 706(2)(A), (C) – Against All Defendants
(Contrary to Law and In Excess of Statutory Authority)

147. Plaintiffs restate and incorporate by reference the allegations above.

148. Congress provided Defendants with the authority to "conduct a special focus program for enforcement of requirements for hospice programs that the Secretary has identified as having substantially failed to meet applicable requirements of [chapter 7, Title 42, U.S. Code]," which provides the requirements for hospice participation in the Medicare program. 42 U.S.C. § 1395i-6(b)(1).

149. On its face, the authorizing statute permits Defendants to establish a Special Focus Program that identifies hospices for enforcement based only on their having "substantially failed" to meet the Medicare requirements. *See* 42 U.S.C. § 1395i-6(b)(1).

150. It is not a requirement of Medicare certification that hospices must achieve a certain score on those quality measures.

[133] Ex. 2, Lund Person Decl., ¶¶ 29-40.

151. Defendants acted contrary to 42 U.S.C. § 1395i-6(b)(1) and in excess of their statutory authority by promulgating the Hospice Special Focus Program Final Rule and List that targeted hospices based on CAHPS scores and HCI measures, rather than based solely (or at all) on findings of hospices to have been noncompliant with Medicare requirements.

152. The Hospice Special Focus Final Rule and List are contrary to law, were issued in excess of statutory authority, and are therefore unlawful.

COUNT TWO
Violation of 5 U.S.C. § 706(2)(A) – Against All Defendants
(Arbitrary and Capricious)

153. Plaintiffs restate and incorporate by reference the allegations above.

154. CMS's Final Rule, which establishes the Special Focus Program and the algorithm that relies on HCI and CAHPS scores, is a final agency action because it consummates the agency's rulemaking and has legal consequences for hospice programs.

155. The Hospice Special Focus Program List, along with the underlying data, is final agency action because it consummates the CMS's selection of hospices for the SFP in 2025 and creates legal consequences, including removing "deemed" status and imposing additional surveys on selected hospice providers.

156. Plaintiffs are adversely affected and aggrieved by the promulgation and enforcement of the Hospice Special Focus Final Rule and List.

157. "The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). Agency action is "arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the

agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

158. The Hospice Special Focus Program Final Rule and Hospice Special Focus Program List are arbitrary and capricious for multiple reasons, including but not limited to the following.

159. *First*, in promulgating the Final Rule and implementing the Final Rule through the List, CMS has "relied on factors which Congress has not intended it to consider." *State Farm*, 463 U.S. at 43. CMS has identified hospice providers with CAHPS and HCI scores that do not measure compliance with Medicare requirements. Even if CAHPS and HCI scores were permissible factors (they are not), CMS has offered no explanation for how using CAHPS and HCI scores help it identify hospices with records of noncompliance, the "quality Congress deemed important in" § 1395i-6(b)(1). *Louisiana v. United States Dep't of Energy*, 90 F.4th 461, 475 (5th Cir. 2024).

160. CMS's arbitrary approach to Medicare requirements has manifested in other ways. CMS can *select* hospices for the Special Focus Program based on CAHPS and HCI scores, but the Final Rule's criteria for *completing* the Special Focus Program relate only to Medicare requirements. 42 C.F.R. § 488.1135(d). That is, a hospice is deemed to have "completed" the Special Focus Program when it has either (a) completed two surveys within 18 months with no condition-level deficiencies and has no pending complaint surveys or (b) returned to substantial compliance with all requirements, *id.*, even though some of the hospices selected for the Special Focus Program were never found to be out of substantial compliance in the first place. "Illogic and internal inconsistency"—such as selecting hospices

based on CAHPS and HCI scores but grading them on Medicare requirements—"are characteristic of arbitrary and unreasonable agency action." *Chamber of Com. of United States of Am. v. United States Dep't of Lab.*, 885 F.3d 360, 382 (5th Cir. 2018).

161. Indeed, the Hospice Special Focus Program list includes six hospice providers with no condition level deficiencies or substantiated complaints in the past three years. Given Congress' direction to identify hospices that substantially fail Medicare requirements, CMS's selection of six hospice programs with unbroken records of substantial compliance for the Special Focus Program is arbitrary and capricious.

162. *Second*, CMS failed to explain adequately why its algorithm uses absolute numbers of condition level deficiencies and substantiated complaints rather than scaling them by beneficiaries served. CMS overlooked fundamental aspects of the problem and failed to articulate a satisfactory explanation for its position. It did not explain why a hospice provider's absolute number of substantiated complaints measures its performance relative to other hospice providers. Nor did CMS confront the downside of not identifying the worst performing hospices. Because the selection is relative based on overall algorithm scores, flaws in the selection criteria prevent CMS from identifying the worst performing hospices for the Special Focus Program, while misleading Medicare beneficiaries and wasting resources on increased oversight for providers that do not need it.

163. *Third*, CMS has also failed to explain adequately its decision to assign average HCI scores to hospice programs that do not report HCI data. CMS acknowledged that approximately 21% of hospices did not report HCI scores and that "hospice providers that did not have a publicly reported HCI score were significantly less likely to be identified in the candidate list of the SFP," and that "[t]his suggests that the algorithm may be limited in its

ability to identify poor performing hospices with under 20 discharges over two years." 88 Fed. Reg. at 77,807. Using an admittedly flawed HCI metric will likely leave poor performing small hospices out of the Special Focus Program and, as a corollary, put better performing larger hospice providers in the Program. This works unnecessary reputational harm, misinforms Medicare beneficiaries about provider quality (overall and relatively), and does not focus enforcement resources on the right set of hospices. Because CMS did not confront the significant downsides to HCI scores, CMS has failed to "articulate a satisfactory explanation for its action." *State Farm*, 463 U.S. at 43.

164. *Fourth*, CMS's Hospice Special Focus Program List has disregarded the Final Rule, made errors in applying the algorithm for selecting hospices, or both. The Final Rule states that "[s]election of hospices for the SFP is made based on the *highest aggregate scores* based on the algorithm used by CMS." 42 C.F.R. § 488.1135(b)(1) (emphasis added). CMS has not included the top 50 scoring hospices. CMS also made demonstrable errors in identifying hospice providers' substantiated complaints. As a result, the Hospice Special Focus Program is either arbitrary and capricious for disregarding the Final Rule or for lacking the support of substantial evidence.

165. Plaintiffs have suffered and will continue to suffer irreparable harm as a result of Defendants' violations of 5 U.S.C. § 706(2)(A).

166. The Final Rule and List are arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law and are therefore invalid under 5 U.S.C. § 706(2)(A).

167. Plaintiffs are entitled to injunctive and declaratory relief to remedy Defendants' unlawful conduct, as well as all other relief as set forth in its Prayer for Relief. *See* 5 U.S.C. § 705.

COUNT THREE
Violation of 5 U.S.C. § 706(2)(D) and 42 U.S.C. § 1395hh – Against All Defendants
(Promulgated Without Observance of Procedure Required by Law)

168. Plaintiffs restate and incorporate by reference the allegations above.

169. Under the APA, a court must set aside agency action that was implemented "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

170. The Medicare Act requires public notice and comment for any "rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [Medicare]." 42 U.S.C. § 1395hh(a)(2).

171. As part of this requirement, the agency must provide notice of any proposed rulemaking, followed by an opportunity for the public to provide comments. 42 U.S.C. § 1395hh(b)(1).

172. When scientific studies or "critical factual material" provide the basis of a rule, an agency gives deficient notice by failing to make those sources available "in order to afford interested persons meaningful notice and an opportunity for comment." *See Texas v. U.S. Env't Prot. Agency*, 389 F. Supp. 3d 497, 505 (S.D. Tex. 2019) (quoting *Air Transp. Ass'n of Am. V. FAA*, 169 F.3d 1, 7 (D.C. Cir. 1999)).

173. CMS referenced in the Special Focus Program Proposed Rule its "analysis of CYs 2019 to 2021 CAHPS Hospice Survey data," and discussed how that analysis impacted its decision about how to treat the CAHPS score in the Special Focus Program algorithm, with a particular focus on how to treat hospices that did not report a CAHPS score.

174. CMS failed to provide commenters with access to these above-referenced analyses—critical material used to develop the Special Focus Program algorithm—thereby denying them a meaningful opportunity to comment on the Special Focus Program Proposed Rule.

175. CMS likewise failed to provide commenters with access to its data files on condition-level deficiencies and substantiated complaints. Commenters had no meaningful opportunity to comment on the CMS's collection of data on condition-level deficiencies and substantiated complaints, substantial components of the algorithm for selecting the Hospice Special Focus Program.

176. The Final Rule was promulgated without observance of procedure required by law and is therefore invalid.

APPLICATION FOR PRELIMINARY INJUNCTIVE RELIEF OR A STAY UNDER APA § 705[134]

177. Plaintiffs restate and reincorporate by reference the allegations stated above.

178. Plaintiffs have suffered and will continue to suffer at least three forms of irreparable injury from Defendants' unlawful actions—the Hospice Special Focus Program Final Rule and the Hospice Special Focus Program List. *First*, Defendants' unlawful actions have caused and will continue to cause reputational harm to Houston Hospice and the members of the Association Plaintiffs. *Second*, Defendants' unlawful actions will impose increased and unrecoverable compliance costs on Houston Hospice and members of the Association Plaintiffs, who must comply with increased surveys as a result of their unlawful inclusion in the Hospice Special Focus Program. *Third*, Defendants' unlawful actions deprive

[134] In accordance with Local Rule 7.1.D, undersigned counsel will confer with defendants' counsel regarding this application for a preliminary injunction once defendants' counsel are identified after service of this Complaint.

Houston Hospice and members of the Association Plaintiffs "deemed status" under Medicare—a statutory entitlement. In the above allegations and supporting declarations, Plaintiffs have established that each such harm is actual and imminent, as well as irreparable.

179. There is no adequate remedy at law for the unlawful Hospice Special Focus Program Final Rule and Hospice Special Focus Program List. A "plaintiff cannot recoup money damages from a federal agency on account of its sovereign immunity." *Mock v. Garland*, 697 F. Supp. 3d 564, 579 (N.D. Tex. 2023).

180. There is a substantial likelihood that Plaintiffs will prevail on the merits of their APA claims. The Hospice Special Focus Program Final Rule and Hospice Special Focus Program List are contrary to law, in excess of Defendants' statutory authority, arbitrary and capricious, and procedurally invalid. In the above allegations and supporting declarations, Plaintiffs have established that they are substantially likely to prevail on the merits of their APA claims.

181. "The balance-of-harms and public-interest factors merge when the government opposes an injunction." *Career Colleges & Sch. of Texas v. United States Dep't of Educ.*, 98 F.4th 220, 254 (5th Cir. 2024). While Plaintiffs will continue to suffer irreparable harm absent an injunction, Defendants have no interest in perpetuating unlawful agency action such as the Hospice Special Focus Program Final Rule and the Hospice Special Focus Program List. *Texas v. United States*, 40 F.4th 205, 229 (5th Cir. 2022). And the public interest favors government agencies abiding by federal law. *Id.* In the above allegations and supporting declarations, Plaintiffs have established that the balance of harms and public interest weigh in favor of injunctive relief.

182. Plaintiffs therefore request a preliminary and permanent injunction under Federal Rule of Civil Procedure 65 or a stay of agency action under APA § 705 that requires Defendants (i) to refrain from implementing the Final Rule and its algorithm; (ii) to rescind the selections for the Hospice Special Focus Program; (iii) to withdraw the Hospice Special Focus Program List and underlying data; (iv) to post in their place a notice that the Hospice Special Focus Program Final Rule and List have been stayed by a federal district court; and (v) to refrain from further selecting hospices for inclusion in the Hospice Special Focus Program or publishing the Hospice Special Focus Program List and underlying data.

183. Plaintiffs ask the Court to set their application for preliminary injunction for a hearing and, after the hearing, to issue a preliminary injunction against Defendants.

184. Plaintiffs ask the Court to include the application for permanent injunctive relief in the Court's final determination of the merits and, after such determination, to issue a permanent injunction, as well as to provide Plaintiffs with the other relief they have requested.

PRAYER FOR RELIEF

WHEREFORE, Provider respectfully requests that the Court:

A. Hold unlawful and set aside the Hospice Special Focus Program Final Rule under 5 U.S.C. § 706(2);

B. Hold unlawful and set aside the Hospice Special Focus Program List under 5 U.S.C. § 706(2);

C. Preliminarily and permanently enjoin Defendants from enforcing the Hospice Special Focus Program Final Rule;

D. Preliminarily and permanently order Defendants (i) to refrain from implementing the Final Rule and its algorithm; (ii) to rescind the selections for the Hospice

Special Focus Program; (iii) to withdraw the Hospice Special Focus Program List and underlying data; (iv) to post in their place a notice that the Hospice Special Focus Program Final Rule and List have been stayed by a federal district court; and (v) to refrain from further selecting hospices for inclusion in the Hospice Special Focus Program or publishing the Hospice Special Focus Program List and underlying data;

E. Award attorneys' fees and costs to Plaintiffs; and

F. Award any other relief as the Court deems just, equitable, and proper.

Dated: January 16, 2025

Respectfully submitted,

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